



Attorney Docket No.: 5776.204-US

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hansen et al.

Application No.: 09/872,127

Group Art Unit: 1614

Filed: June 1, 2001

Examiner: Jerome D. Goldberg

Confirmation No: 1919

Bel
7-22-03

For: Use of N-Substituted Azaheterocyclic Compounds for the Manufacture of a
Pharmaceutical Composition for the Treatment of Indications Related to
Angiogenesis

RESPONSE

Commissioner for Patents
Washington, DC 20231

Sir:

This paper is submitted in response to the Office Action, Paper Number 9,
mailed January 9, 2003, having a shortened statutory period for reply set to expire April
9, 2003. Enclosed herewith is a petition for an Extension of Time pursuant to 37 CFR
§1.136(a) for a period of three (3) months to extend the time for reply to July 9, 2003,
to permit timely filing of this Amendment/Response.

The Examiner states in the Office Action Summary that claims 1-34 are
pending in the application, with claims 6-33 withdrawn from consideration as being
drawn to non-elected subject matter. The Examiner further states claim 3 is objected to
and claims 1, 2, 4, 5 and 34 are rejected.

The Examiner has rejected claims 1, 2, 4, 5 and 34 under 35 USC §112,
first paragraph because the specification, while being enabling for specific cancers
disclosed, does not reasonably provide enablement for the terms "a condition related to
angiogenesis" and "cancer".

Applicant respectfully traverses the Examiner's view that the

specification of the application does not provide reasonable enablement. Applicant believes the present application adequately explains how to make and use the invention to one of ordinary skill in the relevant art. This person of ordinary skill is presumed to be aware of all of the pertinent prior art. Applicant is not required to disclose what the skilled already possess. Nothing more than objective enablement is required.

Applicant has discovered a novel class of compounds which when tested, resulted in a decrease in the vessel area of neovascularization of 30-50% (specification as filed, page 55, lines 23-24). Many diseases and/or conditions have been identified wherein angiogenesis is an etiological, symptomatic or normal-state component. Several of these angiogenesis related conditions are exemplified in the specification at page 1, lines 10-11, 21-23 and 26-28. With respect to cancer, developing tumors depend on angiogenesis for the formation of the blood vessels necessary to support their growth. This phenomenon was first observed in 1907 by Goldman et al. (Proc R. Soc. Med., 1:1, 1907). By the 1970's the therapeutic implication of angiogenesis inhibition was widely known (Folkman, J. N. Engl. J. Med. 285:1182-1186, 1971). Applicant has enclosed two review articles published in 1996 which highlight the clinical significance of inhibiting angiogenesis. Applicant submits one skilled in the relevant art would be aware of what conditions are related to angiogenesis and the types of cancer which would be impacted by treatment with a compound that inhibits neovascularization. Applicant believes providing a list of specific cancers as suggested by the Examiner would unjustly limit the scope of the claimed invention. There is ample guidance in the existing literature for one skilled in the relevant art to determine, without undue experimentation, which conditions related to angiogenesis would be impacted by administration of a compound of the present invention.

The Examiner states that "[t]he term "a condition related to angiogenesis" reads on "cancer" (see claim 2)." Applicant respectfully submits that claim 2 is dependent on claim 1 and provides further limitation to claim 1 by restricting the sphere of conditions related to angiogenesis to those in which the angiogenesis is a component of a cancer.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 2, 4, 5 and 34 under 35 USC §112, first paragraph.

The Examiner has rejected claims 1, 2, 4, 5 and 34 under 35 USC

§103(a) as being unpatentable over Jorgensen et al. WO 96/31497.

Applicant respectfully traverses the Examiner's rejection that the pending claims are obvious over Jorgensen et al. WO 96/31497 and therefore unpatentable. The Examiner states that WO 96/31497 teaches a position isomer of a compound of the present invention for the treatment of acute pain, such as the pain experienced by some cancer patients. The Examiner further states that one skilled in the art would be motivated to administer the position isomer of the present invention with a reasonable expectation that the position isomer would be effective in treating the cancer.

Applicant respectfully notes the Examiner has not provided information regarding where in Jorgensen et al. WO 96/31497 one would find suggestion or motivation to administer an isoform of a compound to treat the underlying disease that is the cause of the pain. Applicant is unsure why one of ordinary skill in the art would have the expectation that an analgesic compound would be reasonably successful in treating the causative disease.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 2, 4, 5 and 34 under 35 USC §103.

The Examiner has objected to claim 3 as being dependent on a rejected claim. Applicant respectfully requests reconsideration and withdrawal of the objection in light of the above discussion.

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this response or application.

Respectfully submitted,



Date: July 9, 2003

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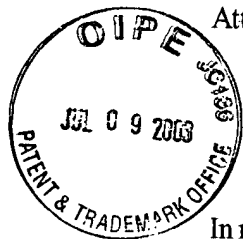


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CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

1. Petition and Fee for Extension of Time – 3 months (in duplicate)
2. Response
3. Cited Articles (2)

is being deposited with the United States Postal Service as Express Mail Label No. EV 246877832
US in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on July 9, 2003

Dolly Kapadia
(name of person mailing paper)

Dolly Kapadia
(signature of person mailing paper)